

Appeal Nos. 2015-1672, -1673, -1674, -1712

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NUVASIVE, INC.,

Appellant,

v.

MEDTRONIC, INC.,

Cross-Appellant,

Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board in Nos. IPR2013-00507, -00508.

**BRIEF FOR INTERVENOR—DIRECTOR OF THE
UNITED STATES PATENT AND TRADEMARK OFFICE**

THOMAS W. KRAUSE

Acting Solicitor

SCOTT C. WEIDENFELLER

Acting Deputy Solicitor

KRISTI L. R. SAWERT

JOSEPH MATAL

Associate Solicitors

Office of the Solicitor

Mail Stop 8, P.O. Box 1450

Alexandria, Virginia 22313-1450

(571) 272-9035

*Attorneys for the Director of the United
States Patent and Trademark Office*

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REPRESENTATIVE CLAIM

1. A spinal fusion implant of non-bone construction positionable within an interbody space between a first vertebra and a second vertebra, said implant comprising:

an upper surface including anti-migration elements to contact said first vertebra when said implant is positioned within the interbody space, a lower surface including anti-migration elements to contact said second vertebra when said implant is positioned within the interbody space, a distal wall, a proximal wall, a first sidewall and a second sidewall, said distal wall, proximal wall, first sidewall, and second sidewall comprising a radiolucent material;

wherein said implant has a longitudinal length greater than 40 mm extending from a proximal end of said proximal wall to a distal end of said distal wall;

wherein a central region of said implant includes portions of the first and second sidewalls positioned generally centrally between the proximal wall and the distal wall, at least a portion of the central region defining a maximum lateral width of said implant extending from said first sidewall to said second sidewall, *wherein said longitudinal length is at least two and half times greater than said maximum lateral width;*

at least a first fusion aperture extending through said upper surface and lower surface and configured to permit bone growth between the first vertebra and the second vertebra when said implant is positioned within the interbody space, said first fusion aperture having: a longitudinal aperture length extending generally parallel to the longitudinal length of said implant, and a lateral aperture width extending between said first sidewall to said second sidewall, wherein the longitudinal aperture length is greater than the lateral aperture width; and

at least three radiopaque markers; wherein a first of the at least three radiopaque markers is at least partially positioned in said distal wall, a second of said at least three radiopaque markers is at least partially positioned in said proximal wall, and a third of said at least three radiopaque markers is at least partially positioned in said central region.

A3-4 (emphases on disputed claim limitations added).

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STATEMENT OF RELATED CASES

The Director adopts NuVasive's statement of related cases. The Director is not aware of any other appeal in connection with this proceeding that has previously been before this or any other court, or of any other case pending in this or any other court that will directly affect or be directly affected by this Court's decision in this appeal.

I. STATEMENT OF THE ISSUES

The Director has intervened in this case for the limited purpose of addressing patent-owner NuVasive's procedural challenges to the Board's management of these inter partes reviews. *See* 35 U.S.C. § 143. NuVasive contends that the Board committed legal error by relying on a "new ground" of unpatentability and violated NuVasive's procedural rights by admitting particular rebuttal evidence and arguments while denying NuVasive's requests to reply.

The issues addressed by the Director in this appeal are:

1. Whether the "new ground" doctrine applies to inter partes review;
2. Whether NuVasive received adequate due process in these inter partes reviews; and
3. Whether the Board exceeded its authority when it performed calculations to confirm that the prior art discloses the claim limitations at issue.

II. STATEMENT OF THE CASE AND FACTS

The private parties in this case are competitors in the field of spinal implants. NuVasive, Inc. ("NuVasive") owns U.S. Patent No. 8,187,334 ("the '334 patent"). Medtronic, Inc. ("Medtronic") filed two petitions with the U.S. Patent and Trademark Office ("USPTO") to institute inter partes reviews of the '334 patent. The USPTO granted Medtronic's petitions in part, instituting two inter partes reviews: (1) in IPR2013-00507, claims 1-5, 10, 11, 14, 15, and 18-28

for obviousness over Frey and Michelson, A00232; and (2) in IPR2013-00508, claims 1-5, 10, 11, and 14-28 for obviousness over “Baccelli, Michelson, and any one of SVS or Telamon,” A05832. The Patent Trial and Appeal Board (“Board”) ultimately issued two final written decisions concluding that claims 1-5, 10, 11, 14-17, and 19-28 were unpatentable under 35 U.S.C. § 103, but that claim 18 was not shown to be unpatentable over the prior art the Board considered. A00001-16 (IPR2013-00507); A00017-35 (IPR2013-00508).

1. Medtronic filed two petitions for inter partes review, each relying on Michelson to teach certain limitations of claim 1

In its first petition, Medtronic alleged that claims 1-3, 10, 14, 15, and 19-28 were unpatentable for anticipation over Frey.¹ A00134-154. Medtronic also argued that claims 1-5, 10, 11, 14, 15, and 18-28 would have been obvious over Frey in view of Michelson.² A00170-176. Frey discloses spinal fusion implants and devices for inserting the implant into the spinal disc space between adjacent vertebrae. A00699-768. Michelson also discloses spinal fusion implants. A00777-793.

As to the ground of anticipation, Medtronic asserted that Frey disclosed all

¹ U.S. Patent Application Publication No. 2002/0165550 (filed Apr. 10, 2002) (published Nov. 7, 2002). A00699-768.

² U.S. Patent No. 5,860,973 (filed Oct. 30, 1996) (issued Jan. 19, 1999). A00777-793.

the limitations of claim 1, including the limitation that the length of the implant measures at least 40 mm. Medtronic relied on Frey's disclosure that the implant's length was "sufficient to span the disc space." A00138 (citing A00757, ¶ 0130). Given that vertebrae generally are longer than 40 mm, Medtronic reasoned, Frey's implant necessarily had to be longer than 40 mm to span the disc space. *Id.* Medtronic also argued that the implant illustrated in Figure 66 of Frey satisfied the limitation requiring that the claimed implant have a relatively long and narrow shape: "length [that] is at least two and [a] half times greater than said maximum lateral width." A00139 (citing A00762, ¶ 0167).

As to the ground of obviousness, Medtronic asserted that Michelson's implants also satisfied many of the limitations of claim 1, including a length of greater than 40 mm. A00171. To the extent that Frey's implants were not inherently at least 40 mm long, Medtronic argued, a skilled artisan would have been motivated to modify those implants "to have the longitudinal length explicitly disclosed in Michelson so that the implant could sufficiently span the lumbar disc space." *Id.* (citing A00757, ¶ 0130). Medtronic also pointed out that Michelson's implants have "dimensions that are longer than wide," and supported that statement with a citation to Michelson's written description at column 10, line 6 to column 11, line 15. A00172 (citing A00790-91).

In its second petition, Medtronic alleged in relevant part that claims 1-5, 10, 11, and 14-28 would have been obvious over the SVS-PR brochure³ in view of Michelson and other prior art, and that the same claims would have been obvious over Telamon⁴ in view of Michelson and other prior art. A05707-71. Medtronic relied on Michelson to teach an implant greater than 40 mm in length for both grounds of obviousness, but relied on the primary references themselves to teach a longer-than-wide implant. *See* A05724-33; A05750-56.

In its preliminary responses, NuVasive focused on the alleged failure of the prior art to teach or suggest an insert having a length of at least 40 mm. A00189-218; A05781-819. As to the first petition, NuVasive alleged that Frey did not inherently teach an implant longer than 40 mm, and that lengthening Frey's implant in view of Michelson would render Frey's invention inoperable. A00201-211. And as to the second petition, NuVasive again alleged that none of the prior art combinations provided an implant having a length greater than 40 mm. A5804-16.

³ Synthes Spine, *Vertebral Spacer-PR*, 2002. A06422-23.

⁴ "Telamon" refers collectively to the Telamon brochure and the Telamon implantation guide. *See* Medtronic Sofamor Danek USA, Inc., *Telamon VERTE-STACK PEEK Vertebral Body Spacer*, 2003 (A06424-25); Medtronic Sofamor Danek USA, Inc., *Telamon Posterior Impacted Fusion Devices*, 2003 (A06426-35).

The Board instituted two inter partes reviews: (1) in IPR2013-00507, claims 1-5, 10, 11, 14, 15, and 18-28 for obviousness over Frey and Michelson, A00232; and (2) in IPR2013-00508, claims 1-5, 10, 11, and 14-28 for obviousness over “Bacelli, Michelson, and any one of SVS or Telamon,” A05832.

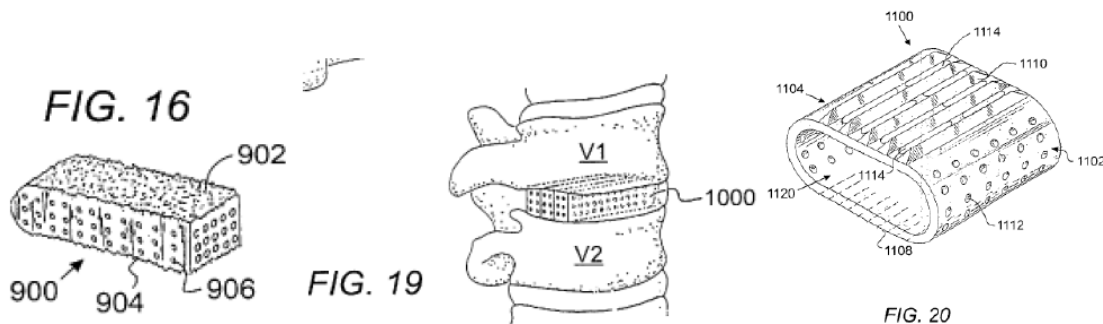
In IPR2013-00507, the Board found that Medtronic had not demonstrated a reasonable likelihood of prevailing on the merits, *see* 35 U.S.C. § 314(a), on most of its proposed grounds of unpatentability. *See* A00226-27. The Board found, however, that Medtronic’s proposed grounds of unpatentability for claims 1-5, 10, 11, 14, 15, and 18-28 based on the combination of Frey and Michelson satisfied the § 314(a) standard. *See* A00227-32. Specifically, the Board agreed with Medtronic that it would have been obvious to lengthen Frey’s implant to at least 40 mm, and rejected NuVasive’s argument that such a modification would render Frey’s insert inoperable. A00227-30. Similarly, in IPR2013-00508, the Board agreed with Medtronic that it would have been obvious to apply Michelson’s length to either the SVS-PR or Telamon inserts. A05829-30. Thus, the Board instituted inter partes review of claims 1-5, 10, 11, and 14-28 based on the combination of Bacelli, Michelson, and SVS-PR or Telamon. A05832.

2. During trial, the parties disputed whether Michelson taught a narrow implant

After its decision to institute the inter partes reviews, the Board conducted full trials according to its rules. *See generally* 37 C.F.R. §§ 42.120-42.123.

NuVasive filed responses in both proceedings, and Medtronic replied. *See* A00268-318 (IPR2013-00507 response); A05874-940 (IPR2013-00507 response); A00338-61 (IPR2013-00507 reply); A05961-84 (IPR2013-00508 reply). Oral argument was consolidated for both inter partes reviews. *See* A00511.

In IPR2013-00507, NuVasive argued that even if it would have been obvious to combine the teachings of Frey and Michelson, the resulting implant would not possess the claimed dimensions. A00310-13. NuVasive first emphasized that Michelson primarily taught “cylindrical dowel-style implants,” and reproduced figures of some of those embodiments. A00289 (showing Figs. 1, 8, 9, 12, 13, and 15b). NuVasive acknowledged that Michelson teaches “more rectangular implants,” A00289, and reproduced three “[f]igures of the more rectangular implants”:



Ex. 1005, Figs. 16, 19, 20

A00290 (showing Figs. 16, 19, and 20).

NuVasive then argued that, regardless of shape, Michelson’s implants were long and wide, instead of long and narrow, for a specific purpose: “The Michelson

patent proposes large implants (both length and width) in an attempt to maximize the surface area of contact with the vertebrae.” A00290; *see also* A00310.

NuVasive emphasized that Michelson’s preferred rectangular embodiment has “a width in the range of 24 mm to 32 mm, with the preferred width being 26 mm; and a length in the range of 32 mm to 50 mm, with 42 mm being the preferred length.” A00291 (citing A00790, col. 10, ll. 41-46). NuVasive postulated that “Michelson proposes implants in which the width . . . is quite large even compared to the largest dimension (the length), thereby providing an implant that is both long and wide[,] to fulfill Dr. Michelson’s intended purpose of an ‘oversized’ spinal implant.” A00291-92.

Michelson, NuVasive continued, “never proposes” a long and narrow implant, and “certainly does not propose any implants with a length to width ratio of 2.5:1.” A00292. To support that contention, NuVasive pointed to the declaration of its expert witness, Dr. Hansen A. Yuan, M.D. *Id.* (citing A04980-81 & A04993-94). Dr. Yuan declared that “all of the implants disclosed by Michelson . . . require a larger width relative to the length, thereby resulting in a length-to-width ratio of measurably less than 2.5.” A04980 (¶ 94). NuVasive elaborated on that point by calculating the dimensions that would satisfy claim 1: an implant just over 40 mm in length could only have a maximum width of 16 mm, and an implant 45 mm in length could only have a maximum width of 18 mm. A00310. Because

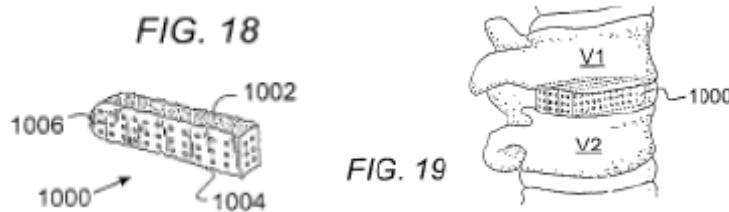
all of Michelson's implants at least 40 mm long are also between 24 and 32 mm wide, Dr. Yuan declared, they do not meet the "long and narrow" limitation of claim 1. A04993 (¶ 110) (citing A00790, col. 10, ll. 41-46). Dr. Yuan concluded that "even if Michelson's proposed lumbar dimensions were implemented on Frey's boomerang implant to provide an implant with a length greater than 40 mm in length, the resulting implant would not have a length-to-maximum-width ratio of 2.5:1 as required by claim 1, but instead would have a length-to-maximum-width ratio 2.08:1 or less." A04994 (¶ 111); *see also* A00311 ("Therefore, if one were to modify Frey according to the dimensions of Michelson, the resulting implant would have a length between 32-50 mm and a width between 24-32 mm.").

In IPR2013-00508, NuVasive argued that the hypothetical combination of SVS-PR and Michelson or Telamon and Michelson would also yield the wrong dimensions for the same reasons. *See* A05921-24; A10608-09 (¶ 59); A10626-28 (¶¶ 93-94); A10647-49 (¶¶ 117-120).

Medtronic disputed NuVasive's reading of Michelson in its replies. Medtronic pointed out that Figure 18 of Michelson depicts a long and narrow implant, and that a person of ordinary skill in the art would understand that the implant illustrated by Figure 18 would have a width in the range of 12 mm to 16 mm. A00351-52; A05973-74. To support that contention, Medtronic relied on a

declaration by its expert witness, Dr. Richard A. Hynes, M.D. A00351-52 (citing A02777-78, ¶ 28 & A02784-86, ¶ 38); A05973-74 (citing A08443-44, ¶ 28).

Dr. Hynes declared that Michelson discloses a relatively long and narrow implant “**1000**” in Figures 18 and 19:



A02777 (¶ 28); A08443-44 (¶ 28); *see also* A00784 (Figs. 18 and 19). Dr. Hynes explained that a skilled artisan would understand that implant **1000** has a width of approximately 12 mm to 16 mm, and that the skilled artisan would come to that conclusion by comparing the relative sizes of insert **1000** (depicted in Figures 18 and 19) and insert **900** (depicted in Figures 16 and 17). A02777 (¶ 28); A08444 (¶ 28).

Specifically, implant **900** has a width “in the range of 24 mm to 32 mm,” Dr. Hynes explained. A02777 (¶ 28) (citing A00790, col. 10, ll. 41-44). And because Michelson shows implant **1000** to be approximately half the width of implant **900**, Dr. Hynes continued, a skilled artisan would understand implant **1000** to have a width of 12 mm to 16 mm (*i.e.*, half of 24 mm to 32 mm). *Id.*; A08444 (¶ 28); *see also* A02784-85 (¶ 38) (explaining how the skilled artisan could compare the columns of openings **906** and **1006** on the respective proximal ends of the implants

to conclude that implant **1000** has a lateral width of at least half that of implant **900**).

Dr. Hynes also pointed out that Michelson explicitly describes implant **1000** as having a “narrower width” than implant **900**, and that Michelson instructs that implant **1000** “may” be used in modular fashion for insertion into the disc space. A02777 (¶ 28) (citing A00790, col. 10, ll. 49-54); A08444 (¶ 28). Based on this permissive language, Dr. Hynes explained, the skilled artisan would understand that implant **1000** could be inserted into the spinal disc space as a single, narrow implant (depicted in Figure 18), or as a modular, wide implant (depicted in Figure 19). A02777 (¶ 28); A08444 (¶ 28). And when inserted individually, the width of the implant “would potentially be as small as one third the preferred range of widths discussed above given three of them being shown side-by-side in Fig. 19.” A02785 (¶ 38).

For these reasons, Dr. Hynes disagreed with Dr. Yuan’s assertion that Michelson does not teach a “long and narrow” implant: “Dr. Yuan’s conclusion . . . wholly fails to take into account Michelson’s disclosure of long narrow implants, exemplified in Figure 18 and identified as implant **1000** and discussed in his specification.” A02784-85 (¶ 38). Thus, contrary to Dr. Yuan’s statements, Michelson discloses an implant having a length two-and-a-half times its width. *Id.*; *see also* A08444 (¶ 28).

3. Following briefing, the Board refused NuVasive's requests to respond once more to Medtronic's grounds of unpatentability

Following briefing, the Board held a conference call to consider NuVasive's requests to file surreplies, or alternatively, motions to strike Medtronic's replies.

The Board issued orders the following day denying NuVasive's requests. *See* A0368-72; A05991-95. In the orders, the Board first noted that "whether a reply contains arguments or evidence that is outside the scope of a proper reply under 37 C.F.R. § 42.23(b) is left to the determination of the Board." A00369; A05992.

The Board then explained that it would consider whether Medtronic's replies presented "improper arguments and evidence" when preparing the final written decisions. A00369; A05992. If Medtronic's replies violated Rule 42.23(b), the Board stated, then the Board would "exclude the reply and related evidence" as necessary. A00369; A05992.

The Board noted, however, that NuVasive could cross-examine Medtronic's reply declarants, and file motions for observation to "draw the Board's attention to relevant cross-examination testimony of a reply witness." A00369-70; A05992-93. NuVasive deposed Dr. Hynes seven days after the Board's order, *see, e.g.*, A10989, and filed motions for observation as the Board suggested. Neither motion addressed Figures 18 or 19 of Michelson. *See* A00435-49 (IPR2013-00507), A06047-60 (IPR2013-00508).

The Board heard oral argument for IPR2013-00507 and IPR2013-00508 together. A00509. During the argument, each party disputed the propriety of the other's arguments. Of relevance here, NuVasive asserted during its argument that Figure 18 was not a stand-alone implant that could be inserted individually into the spinal disc space. Medtronic objected, and the Board directed NuVasive to limit its arguments to the record:

[NUVASIVE]: . . . And in the reply, they specifically point to the alleged narrower disclosure in Michelson, and then they show it in the vertebral space here. The key of figure 18 and figure 19 is that it is showing a modular implant that is designed to be inserted in modular fashion, again, to create a wide implant.

[MEDTRONIC]: Your Honor, I again object, that is raising a new argument that's not in his response.

[NUVASIVE]: And this was an argument that we brought to the Board's attention, Your Honor, that they raised in reply, and we're just addressing the argument because I will not have an opportunity to address this argument when Mr. Schwartz stands up in reply and points this Board to figures 18 and 19.

JUDGE MEDLEY: But you asked for a surreply and we denied that.

[NUVASIVE]: Correct.

JUDGE MEDLEY: So I think you just need to stick with -- you can point out what they argue, but you should not be responding to it at this hearing.

[NUVASIVE]: I understand, Your Honor.

JUDGE MEDLEY: Their arguments.

[NUVASIVE]: I understand, Your Honor.

A00544 (36:4-24).

During its argument, Medtronic attempted to rebut NuVasive's reliance on Michelson's Figure 19 as teaching a long and wide implant, and NuVasive objected. The Board reminded NuVasive that it would take NuVasive's objections under consideration when preparing the final written decisions:

[MEDTRONIC]: . . . And I would like to go to this discussion of Michelson, and I'm going to bring up the figures from NuVasive's response, at page 28, and let's talk about what Michelson teaches. Now, NuVasive relies on figure 19, that figure in the middle, now I've got my pen instead of my pointer, NuVasive relies on this figure. This is NuVasive's response to say that Michelson teaches a wide implant. Not so. Michelson teaches long, narrow implants as well. As you can see in this figure, there are three long, narrow implants. This is NuVasive's response. They're arguing that it teaches long, wide, but it's showing you long, narrow.

[NUVASIVE]: Your Honor, I'm going to object to this line of argument, because this is something that was never articulated in the petition, it was raised for the first time in reply, we raised this issue with the Court previously and asked for an opportunity to submit a surreply to these types of arguments

JUDGE MEDLEY: We understand your argument, your position, as you've articulated this in several prior conference calls. We are aware of our rule, too, that says that the reply needs to be responsive to the Patent Owner response. So, I think you just have to let the process

take place and we will take it all under advisement when we write our final decision.

[**MEDTRONIC**]: Thank you, Your Honor. And to be clear, I'm not pointing to our reply, I'm pointing to NuVasive's response, which I'm simply rebutting. They don't get an opportunity to just say stuff about the art and mischaracterize it.

A00565-66 (57:12-58:15).

4. The Board issued final written decisions finding that Michelson teaches a "long and narrow" implant

At the close of the proceedings, the Board issued its final written decisions. A00001-16 (IPR2013-00507); A00017-35 (IPR2013-00508). In those decisions, the Board held all claims at issue, except for claim 18, unpatentable as obvious over various combinations of prior art relying on Michelson as a secondary reference. In both decisions, the Board rejected NuVasive's argument that Michelson fails to teach an implant that is both long (over 40 mm) and narrow (length at least 2.5 times width). A00008-9; A00022-23.

The Board first described spinal fusion implant **900** as having a preferred width of 26 mm: "Michelson expressly discloses an implant 'with 42 mm being the preferred length' and a width that 'approximates the depth of the vertebrae,' that measures 'in the range of 24 mm to 32 mm,' with 'the preferred width being 26 mm.'" A00009 (quoting A00790, col. 10, ll. 40-41 & 44-47); A00022-23 (same). Given that disclosure, the Board reasoned that the approximate depth of the

vertebrae is 26 mm. A00009; A00023. The Board then described Michelson's alternative implant **1000** embodiment: "In one embodiment of Michelson, one implant 'has a narrower width such that more than one spinal fusion implant . . . may be combined . . . for insertion within the disc space.'" A00009 (quoting A00790, col. 10, ll. 52-54); A00023 (same).

With that information, the Board concluded that Michelson teaches that implant **1000** has a length two-and-a-half times its width, thus satisfying the "long and narrow" claim limitation. A00009; A00023 & n.5. The Board elaborated: "For example, if the total width of at least two spinal fusion implants measures 26 mm (i.e., the depth of the vertebrae), then each implant would measure $26 \text{ mm} / 2 \text{ implants} = 13 \text{ mm}$ " in width. A00009; A00023. And, the Board noted, that width—when multiplied by a factor of 2.5—is less than the preferred length of the implant. A00009; A00023.

III. SUMMARY OF THE ARGUMENT

Due process in a post-grant proceeding under the America Invents Act is not as rigid as NuVasive portrays it. The USPTO's regulations and practices governing AIA post-grant proceedings provide ample opportunity for a party to receive notice of proposed grounds of unpatentability and the supporting evidence and arguments on which the Board could render a final written decision.

Here, the Board relied in its final written decisions on the same grounds of unpatentability that the Board articulated in its institution decisions. And the Board relied on evidence that Medtronic presented in its petitions and continued to press through the trial phase. NuVasive should have responded completely to that evidence in its patent-owner response, cross-examination of Medtronic's expert witness, and motions for observation given that it put many of the factual disputes implicated by that evidence in issue. The Board did not abuse its discretion by refusing NuVasive's attempts to address that evidence one last time.

NuVasive's argument that the Board exceeded its authority in the final written decisions by explaining Michelson's disclosure lacks merit. The Board acted like any adjudicatory body should—it weighed the evidence and arguments before it and made an ultimate decision of the patentability of NuVasive's claims as it is required to do under the law. NuVasive's failure to successfully rebut Medtronic's obviousness case is not a due-process violation.

IV. ARGUMENT

A. Standard of Review

“This [C]ourt reviews Board decisions using the standard set forth in the Administrative Procedure Act, 5 U.S.C. § 706.” *In re Sullivan*, 362 F.3d 1324, 1326 (Fed. Cir. 2004) (citing *Dickinson v. Zurko*, 527 U.S. 150, 154 (1999)). Under 5 U.S.C. § 706(2)(A), this Court only overturns Board decisions if they “are

arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” *Sullivan*, 362 F.3d at 1326 (citing *In re McDaniel*, 293 F.3d 1379, 1382 (Fed. Cir. 2002)). This Court reviews the Board’s evidentiary rulings “for abuse of discretion, which may be found if the Board violated governing law.” *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1078 (Fed. Cir. 2015).

This Court accepts the Board’s interpretation of USPTO regulations unless that interpretation is “plainly erroneous or inconsistent with the regulation.” *Sullivan*, 362 F.3d at 1326 (quotation omitted); *see also Auer v. Robbins*, 519 U.S. 452, 461-62 (1997); *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945); *In re Lovin*, 652 F.3d 1349, 1353 (Fed. Cir. 2011).

B. The “New Grounds” Doctrine Does Not Apply in Inter Partes Review

NuVasive argues that the Board “erred” by relying on “new grounds” of unpatentability in its final written decisions. Br. at 30-38. To make this argument, NuVasive relies extensively on case law that applies the new-grounds-of-rejection doctrine in appeals from USPTO examinations to the Board. *See, e.g.*, Br. at 31-32 & 36 (citing *Rambus Inc. v. Rea*, 731 F.3d 1248 (Fed. Cir. 2013); *In re Biedermann*, 733 F.3d 329 (Fed. Cir. 2013); *In re Stepan Co.*, 660 F.3d 1341 (Fed. Cir. 2011); *In re Leithem*, 661 F.3d 1316 (Fed. Cir. 2011); *In re Echerd*, 471 F.2d 632 (CCPA 1973)). But as this Court recently explained, the new-grounds doctrine does not apply to inter partes review. *Belden*, 805 F.3d at 1080; *see also*

Dell Inc. v. Acceleron, LLC, --- F.3d ----, 2016 WL 1019075 at *6 (Fed. Cir. Mar. 15, 2016). Instead, the protections provided in the Board’s trial-specific rules and practices, consistent with the APA, “generally protect against loss of patent rights without the required notice and opportunity to respond.” *Belden*, 805 F.3d at 1080.

The new-grounds doctrine and this Court’s case law explaining it apply only to examination and reexamination. In examinations, the proceedings follow a rejection-and-response format. An examiner issues an office action rejecting claims and providing a statement of reasons for the rejection. *See* 35 U.S.C. § 132(a). The applicant has an opportunity to overcome the rejection by submitting arguments and proposing claim amendments. *Id.* If the applicant does not succeed before the examiner, he or she may appeal to the Board, which reviews the examiner’s decision. 35 U.S.C. § 134. In that capacity, the Board sits as an appellate tribunal and is limited to the record developed before the examiner.

The Board may articulate new reasoning and rely on new evidence to sustain the rejection. *See* 37 C.F.R. § 41.50(b). If the Board does so, however, the Board must notify the party that it has entered a new ground of rejection. *Id.* The new-grounds notice allows the party to seek reconsideration from the Board or to return to prosecution before the examiner. *Id.* The new-grounds doctrine, thus, affords a party notice of any new rationale and/or evidence underlying the Board’s decision and an opportunity to respond, either before the Board or the examiner.

This Court, likewise, has applied the new-grounds doctrine in reviewing the Board's decisions in examination proceedings. *See, e.g., Rambus*, 731 F.3d at 1255-56; *Biedermann*, 733 F.3d at 336-37; *Stepan*, 660 F.3d at 1345-46; *Leithem*, 661 F.3d at 1319-20. The concern with new grounds in examinations, as this Court has explained, is that a patent applicant (or reexamination applicant) should be entitled to continue examination proceedings if the applicant "has not had a full and fair opportunity to litigate the Board's actual basis of rejection." *Stepan*, 660 F.3d at 1343.

But, in AIA post-grant reviews, the Board's trial-specific rules and practices provide such "a fair opportunity." *See Belden*, 805 F.3d at 1080. Specifically, those rules and practices provide opportunities for a patent owner to obtain notice of the potential grounds of unpatentability and an opportunity to be heard before the Board issues a final written decision. *Id.*

A review of the procedural framework of an inter partes review demonstrates the array of opportunities. An inter partes review proceeds in two phases. *See St. Jude Med., Cardiology Div., Inc. v. Volcano Corp.*, 749 F.3d 1373, 1375–76 (Fed. Cir. 2014). In the first phase, a requesting party files a petition for inter partes review that sets forth, "in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim." 35 U.S.C.

§ 312(a)(3). A petition must be accompanied by any patents, printed publications, and expert opinions on which the petitioner relies. *Id.* The petition, therefore, is a natural source from which a patent owner receives notice of potential grounds of unpatentability and supporting evidence and arguments.

A patent owner has the opportunity to file a preliminary response to a petition, which provides a patent owner the opportunity to respond to a patentability challenge before the Board decides the petition. 35 U.S.C. § 313; 37 C.F.R. § 42.107(a). The Board reviews the petition and any preliminary response, and issues an institution decision, in which the Board determines whether there is a reasonable likelihood that the petitioner will prevail with respect to at least one challenged claim. *See* 35 U.S.C. § 314(a). The institution decision serves as another source of notice to a patent owner of proposed grounds of unpatentability and potential supporting arguments and evidence.

If the Board institutes review, additional events provide opportunities for a patent owner both to obtain notice of the issues and submit arguments in favor of patentability. A patent owner may take discovery and cross-examine experts who submit declarations on behalf of a petitioner. *See* 37 C.F.R. §§ 42.51(b), (b)(1)(ii). A patent owner may file a patent-owner response, in which the patent owner presents its arguments and expert testimony in support of patentability. 35 U.S.C. § 316(a)(8); 37 C.F.R. § 42.120. Discovery begins immediately after the Board

institutes review. *See* 37 C.F.R. § 42.51(a)(1)(ii); *Office Patent Trial Practice Guide*, 77 Fed. Reg. 48,756, 48,757 (Aug. 14, 2012). But a patent-owner response is not due until three months after institution. 37 C.F.R. § 42.120(b). A patent owner, therefore, has the benefit of taking discovery before filing a patent-owner response and relying on that discovery in the response. Alternatively, “[i]n the event that cross-examination occurs after a party has filed its last substantive paper on an issue, . . . [t]he Board may authorize the filing of observations” on that cross-examination. *Practice Guide*, 77 Fed. Reg. at 48,767-68.

The opportunity for notice and response does not end there. A petitioner has an opportunity to file a reply brief after the patent owner’s response, thus providing the patent owner another opportunity to ascertain the issues in play. 37 C.F.R. § 42.23(b). If a patent owner believes a petitioner has strayed too far from the boundaries of permissible argument and evidence, the patent owner has recourse. A patent owner, for example, may request leave to file a surreply. *See Belden*, 805 F.3d at 1081 & n.5 (“[T]he Board (or its predecessor) has long granted permission to file surreplies despite the absence of any regulation providing for such filings.”). A patent owner also may move to exclude evidence from consideration at trial. 37 C.F.R. § 42.64(c).

This sampling is more than a laundry list. It shows that the USPTO provides an array of mechanisms through which a party receives due process in an AIA

post-grant proceeding. Many of these litigation events provide opportunities for both notice and response. When a patent owner, for example, cross-examines a petitioner's expert, the patent owner has the opportunity to learn about the petitioner's case, and the patent owner has an opportunity to respond to that case by testing the strength of the expert's opinion during cross-examination. Armed with that cross-examination testimony, a patent owner has a further opportunity to respond by presenting advantageous testimony to the Board by filing a motion for observation.

The interactions between the parties, and between the parties and the Board, throughout a trial produces the notice and opportunity to respond. As this Court observed, "the Board's rules and practices establish standards bearing similarities to those often applied in district-court litigation. . . . Those standards are widely employed to provide the required procedural fairness through careful case-specific application." *Belden*, 805 F.3d at 1081-82. For these reasons, the new-grounds doctrine does not apply to inter partes review.

C. NuVasive Enjoyed Adequate Due Process in These Inter Partes Reviews

"The indispensable ingredients of due process are notice and an opportunity to be heard by a disinterested decision-maker." *Abbott Labs. v. Cordis Corp.*, 710 F.3d 1318, 1328 (Fed. Cir. 2013). The Administrative Procedure Act imposes those requirements on the Board. *See Zurko*, 527 U.S. at 154. Under the APA, a

patent owner in an AIA proceeding must receive (1) notice of all “matters of fact and law” pertaining to a patentability challenge, 5 U.S.C. § 554(b)(3); (2) an “opportunity for . . . the submission and consideration of facts [and] arguments . . . [and] hearing and decision on notice,” *id.* § 554(c); and (3) the opportunity “to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts,” 5 U.S.C. § 556(d); *see also Belden*, 805 F.3d at 1080.

The record demonstrates that NuVasive received adequate due process in these inter partes reviews. NuVasive was on notice that Medtronic relied on the disclosure of Michelson’s rectangular-shaped implants to teach the “long and narrow” claim limitations, and NuVasive had opportunities to rebut that evidence, to submit its own evidence and arguments, as well as to cross-examine Medtronic’s expert witness and submit observations on the cross-examination. That NuVasive did not take advantage of some of those opportunities, and that the Board otherwise rejected NuVasive’s proffered evidence and arguments, do not amount to a violation of due process. This Court should reject NuVasive’s arguments to the contrary.

1. Medtronic’s petition relied on Michelson’s disclosure to teach “long and narrow” implants

NuVasive argues that it never had the opportunity to address the length-to-width ratios of Michelson’s implants because Medtronic did not rely on

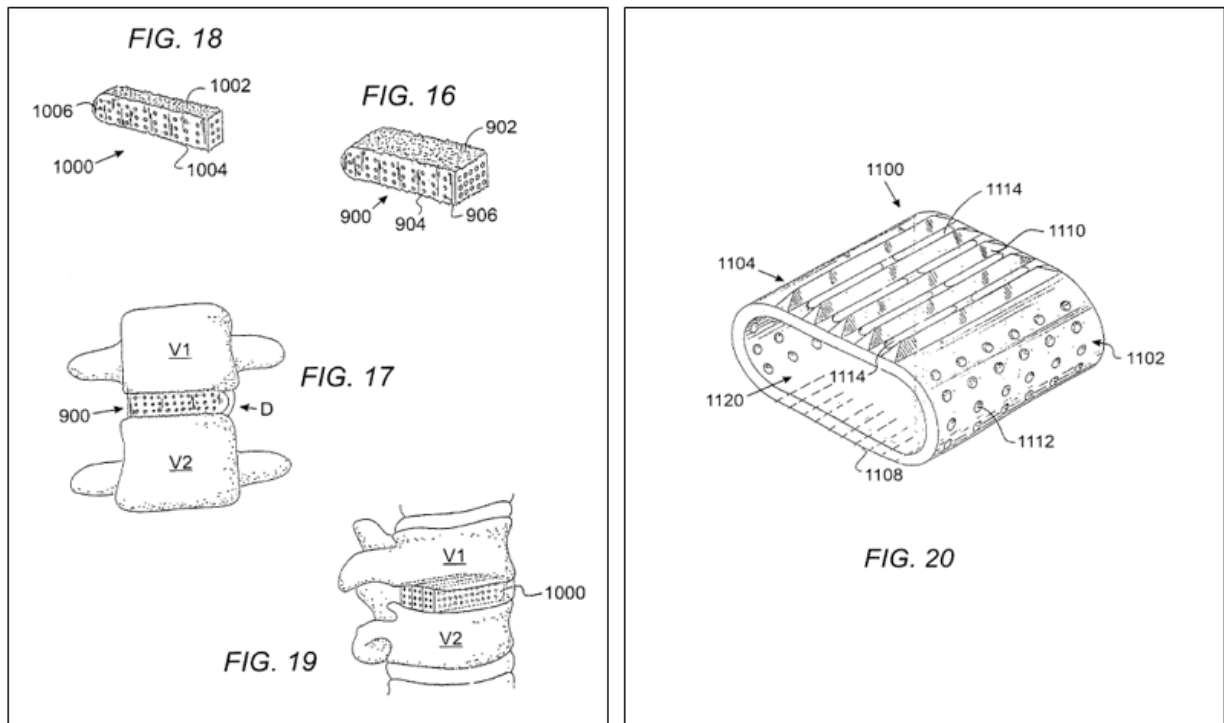
Michelson's dimensions in its petitions. Br. at 36-37. The record belies NuVasive's assertion; Medtronic first identified and relied on Michelson's rectangular-shaped implants in its petitions. Specifically, Medtronic relied on Michelson to the extent that the primary reference did not expressly disclose the claimed "long and narrow" dimensions. In IPR2013-00507, for example, Medtronic pointed out that Frey and Michelson share many of the same features: an elongated shape, dimensions that are longer than wide, and a large internal space. And to support its statement that Michelson teaches a longer-than-wide shape, Medtronic cited to Michelson's written description at column 10, line 6 to column 11, line 15. A00172 (citing A00790-91).

This section of Michelson's disclosure teaches rectangular-shaped implants as alternative embodiments to Michelson's main dowel-shaped implants. A00790-91 (col. 10, l. 6 to col. 11, l. 15). Michelson specifically describes three rectangular implants: (1) implant **900**, that is comprised of a "rectangular block" **901**; (2) implant **1000**, that is "similar to the spinal fusion implant **900**, but has a narrower width"; and (3) implant **1100**, that "has a generally rectangular body with curved sides **1102** and **1104**." *Id.* Michelson further teaches that implant **900** is illustrated in Figures 16 and 17, A00790 (col. 10, ll. 6-8 & 32-36), implant **1000** is illustrated in Figures 18 and 19, *id.* (col. 10, ll. 47-49 & 55-58), and implant **1100** is illustrated in Figure 20, *id.* (col. 10, ll. 59-61). Medtronic did not state or imply

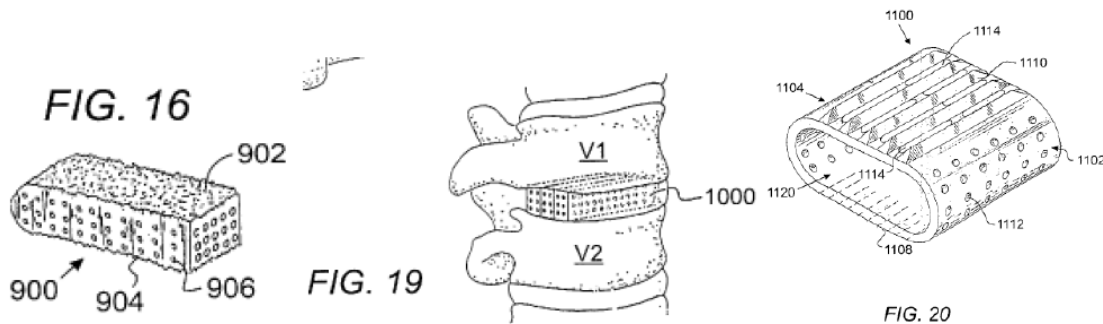
that any of these implants were not “longer than wide.” And thus NuVasive—after reading a mere one-and-a-quarter columns of disclosure—should have been aware of all three of Michelson’s rectangular-shaped embodiments and the figures illustrating them.

Although NuVasive addressed all three implants in its response, it ignored Figure 18. Specifically, NuVasive reproduced Figure 16 (showing implant **900**), Figure 19 (showing three implants **1000** side-by-side), and Figure 20 (showing implant **1100**). A00289-90. But NuVasive did not acknowledge implant **1000** as depicted in Figure 18—despite the fact that Figure 18 appears with these other three figures on the same two pages. A00784-85.

Here is what appears on those adjoining pages (A00784-85) of Michelson:



But here is what NuVasive depicted in its patent-owner response:



Ex. 1005, Figs. 16, 19, 20

A00290; A05904. Thus, NuVasive simply “air brushed” Figure 18 out of its representation of the prior art. NuVasive then restricted its discussion of the five figures to the implants shown in only Figures 16, 19, and 20. A00291-92; A05905-07. And NuVasive concluded by insisting that Michelson “does not propose *any* implants with a length to width ratio of 2.5:1.” A00292 (emphasis added); A05907.

But NuVasive reached that conclusion by *ignoring* the embodiment (implant **1000** as depicted in Figure 18) that shows a long length and narrow width—even though this embodiment was found on the same two pages as the three embodiments that NuVasive *did* analyze. Medtronic clearly stated in its petition that the cited passage of Michelson—which describes only three implants **900**, **1000**, and **1100**—“discloses example lateral fusion implants having . . . dimensions that are longer than wide.” A00172 (citing A00790-91, col. 10, l. 6 to col. 11, line 15). And NuVasive was aware of Medtronic’s reliance on this passage for

teaching “long and narrow” implants because NuVasive analyzed the embodiments that did not meet the claimed length-to-width ratio. Put differently, NuVasive closed its eyes to implant **1000** in Figure 18—the embodiment that does represent the claimed length-to-width ratio. The Board cannot be faulted for NuVasive’s failure to take on implant **1000** and Figure 18 in its patent-owner response.

Nevertheless, NuVasive contends that the Board created a new ground of unpatentability by relying on implant **1000** (as shown in Figure 18) in its final written decisions. Br. at 36-37. NuVasive confuses “grounds” of unpatentability with “evidence” that supports the grounds. A “ground” of unpatentability is a legal theory that, if paired with sufficient “evidence,” establishes a *prima facie* case of unpatentability. The AIA provides that a petition for inter partes review must set forth “the *grounds* on which the challenge to each claim is based, and the *evidence* that supports the grounds for the challenge to each claim.” 35 U.S.C. § 312(a)(3) (emphases added).

Medtronic’s petitions did that by setting forth the grounds of unpatentability as obviousness over a primary reference (*i.e.*, Frey) or references (*i.e.*, Telamon or SVS-PR) in view of Michelson, and by providing the evidence supporting its arguments that Michelson teaches the claimed length-to-width ratio. *See* A00172 (citing A00790-91, col. 10, l. 6 to col. 11, line 15). The Board did not create a “new ground” by relying on the evidence that Medtronic submitted to support the

grounds of unpatentability presented in its petitions.

2. Medtronic’s specific citation to Figure 18 was in fair reply to NuVasive’s argument that Michelson did not disclose “long and narrow” implants

Even if Medtronic first pointed to implant **1000** (as shown in Figure 18) individually in its replies, rather than identifying implants **900**, **1000**, and **1100** collectively (as it did in its petitions), the Board’s reliance on implant **1000** in its final written decisions was proper. Nothing in the AIA or the USPTO’s implementing regulations requires a petitioner to present all evidence or arguments used to challenge patentability in the petition.⁵ Rebuttal in *reply* to a patent owner’s arguments, whether via new testimony, other evidence, or new argument, is entirely proper. *Belden*, 805 F.3d at 1077-78; *see also* 37 C.F.R. § 42.23(b).

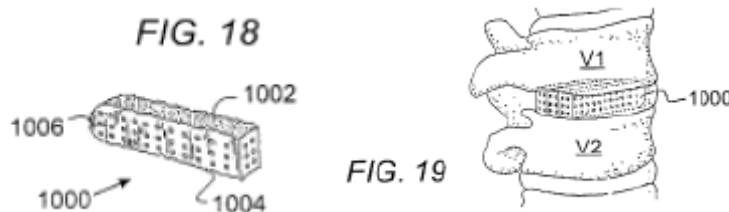
Medtronic’s citation to Figure 18 in its reply directly responded to NuVasive’s resolute position that Michelson taught only “long and wide” spinal fusion inserts. In its patent-owner response, NuVasive contended that Michelson “*never proposes*” a long and narrow implant, and “*certainly does not propose any*

⁵ That a petitioner may not raise new grounds of unpatentability after institution does not mean that the petitioner cannot later offer additional evidence for the grounds on which the Board instituted review. A patent owner should not take refuge in the assumption that the evidence and arguments that the Board addressed in its institution decision are the only fair game in the trial phase. The AIA does not so restrict the trial phase. Indeed, there would be little point in having trials (with discovery) if they were as limited as NuVasive contends.

implants with a length to width ratio of 2.5:1.” A00292 (emphases added). Dr. Yuan echoed NuVasive’s staunch position: “*all* of the implants disclosed by Michelson . . . require a larger width relative to the length, thereby resulting in a length-to-width ratio of measurably less than 2.5.” A04980 (¶ 94) (emphasis added).

Medtronic was allowed to rebut those arguments in its reply—even with new evidence—as this Court held in *Belden*. The petitioner in *Belden* first introduced a rebuttal declaration in its reply. 805 F.3d at 1071. On appeal, the patent owner challenged the Board’s denial of its motion to exclude the declaration as a violation of due process, and as inconsistent with the USPTO’s rules and *Practice Guide*. *Id.* at 1077-78. This Court found the “new” rebuttal evidence to be lawful and fair, and emphasized the additional procedural safeguards offered by the PTAB to address such new evidence during trial. *Id.* at 1078-82.

Just as in *Belden*, Medtronic replied to NuVasive’s contentions with evidence that Michelson depicts a long and narrow implant (implant **1000**), and that a person of ordinary skill in the art would understand that implant **1000**, as illustrated by Figure 18, has a width in the range of 12 mm to 16 mm. A00351-52; A05973-74. Specifically, Medtronic submitted as evidence the declaration of Dr. Hynes, who explained that Michelson discloses the relatively long and narrow implant **1000** in Figures 18 and 19:



A02777 (¶ 28); A08443-44 (¶ 28); *see also* A00784 (Figs. 18 and 19). Dr. Hynes further explained that a skilled artisan would understand that implant **1000** has a width of approximately 12 mm to 16 mm, because Michelson shows implant **1000** as having approximately half the width of implant **900**, which has a width “in the range of 24 mm to 32 mm.” A02777-78 (¶ 28); A08444 (¶ 28); *see also* A02784-85 (¶ 38) (explaining how the skilled artisan could compare the columns of openings **906** and **1006** on the respective proximal ends of the implants to conclude that implant **1000** has a lateral width of at least half that of implant **900**).

Dr. Hynes also rebutted NuVasive’s insinuation that implant **1000** could be used *only* as the modular, wide implant depicted in Figure 19. Dr. Hynes pointed out that Michelson explicitly describes implant **1000** as having a “narrower width” than implant **900**, and that Michelson instructs that implant **1000** “may” be used in modular fashion for insertion into the spinal disc space. A02777-78 (¶ 28) (citing A00790, col. 10, ll. 49-54); A08444 (¶ 28). Based on this permissive language, Dr. Hynes explained, the skilled artisan would understand that implant **1000** could be inserted into the spinal disc space as the single, narrow implant depicted in Figure 18. A02777 (¶ 28); A08444 (¶ 28).

NuVasive contends that the Board erred by relying on this evidence because “it cannot be . . . that if a patent owner specifically identifies a hole in a petitioner’s *prima facie* case, the petitioner then can fill in the hole with a new disclosure, and the patent owner has no opportunity to respond.” Br. at 37. NuVasive’s assertion is incorrect on its face. The statutes and rules governing inter partes review allow the parties to conduct post-institution discovery and file post-institution responses and replies. This structure clearly contemplates that additional evidence will be filed with the post-institution briefs and will be considered by the Board. Indeed, that is the point of discovery.

NuVasive cites to no statute or rule that limits the evidence and arguments that the Board can consider to those specifically presented in the petition for inter partes review. *Cf. Belden*, 805 F.3d at 1079 (“Evidence admitted in rebuttal to respond to the patent owner’s criticisms will commonly confirm the *prima facie* case.”). Nor does NuVasive cite to any statute or rule that requires the Board to give the patent owner the final arguments in these trial-like proceedings. And in any event, the post-institution process that the Board followed in this case—allowing NuVasive to file its responses, allowing Medtronic to reply, and then issuing its final written decisions—conforms exactly to the process prescribed by the AIA. *See* 35 U.S.C. §§ 316(a)(8), (a)(13); *see also* 37 C.F.R. §§ 42.23, 42.120.

This Court’s recent decision in *Dell* does not counsel differently. In *Dell*, the Court vacated and remanded the Board’s conclusion of unpatentability based entirely on new evidence presented at oral argument. 2016 WL 1019075, at *6-7. The Board had dismissed the patent owner’s objections to that new evidence at oral argument, concluding that the petitioner had pointed to the evidence in its reply. *Id.* at *7. This Court disagreed, stating that “the key factual assertion was not in fact made in Dell’s reply, but only at oral argument.” *Id.* The Court did not need to—and expressly did not—“address under what circumstances a cancellation may rely on a key factual assertion made for the first time in a petitioner’s reply.” *Id.* Thus, *Dell* does not affect the outcome of this case; the decision at most holds every Board panel to its word: “No new evidence or arguments may be presented at oral argument.” *Id.* at *6 (quoting *Practice Guide*, 77 Fed. Reg. at 48,768).

3. The Board did not abuse its discretion by denying NuVasive’s attempts to get in the last word

NuVasive contends that the Board denied it due process by “repeatedly preclud[ing]” it from addressing Figure 18. Br. at 36. It is true that the Board made several trial-management decisions refusing NuVasive’s oral requests to file surreplies, to file motions to strike Medtronic’s replies, and to present certain arguments at oral argument. But that is because NuVasive already had the opportunity to address implant **1000** and Figure 18 in its patent-owner response, but did not. *See* A00544 (36:4-24) (characterizing NuVasive’s oral argument

about the “key” of Figures 18 and 19 as an attempt to present a new argument). The Board did not abuse its discretion by denying NuVasive’s attempts to get in the last word.

Again, Medtronic’s petition placed NuVasive on notice of the grounds of unpatentability based on the implants of Michelson, as depicted in Figures 16-20, having “dimensions that are longer than wide.” A00172. And although NuVasive addressed implant **1000** as depicted in Figure 19 in its responses, NuVasive did not address the same implant as depicted in Figure 18. On appeal, NuVasive’s position appears to be that implant **1000** could not be inserted into the spinal disc space as the single implant shown in Figure 18. Br. at 45-46. But if that position justified NuVasive’s exclusion of Figure 18 from its responses, NuVasive should have said so right then and there. NuVasive had the opportunity—and the responsibility—to explain why the “narrower width” embodiment shown in Figure 18 did not actually represent implant **1000** in practice; the Board did not abuse its discretion in refusing to provide NuVasive a second chance to do so after the close of briefing.

But in any event, NuVasive was not without recourse in these inter partes reviews.⁶ As this Court explained in *Belden*, a patent owner can respond to an

⁶ Medtronic filed its replies and the accompanying declaration of Dr. Hynes on September 5, 2014. *See* A00360; A05984. The Board’s order denying

expert declaration newly submitted with a petitioner's reply by "cross-examin[ing] the expert and mov[ing] to file observations on the cross-examination." 805 F.3d at 1081; *see also* 37 C.F.R. § 42.51(b)(1)(ii); *Practice Guide*, 77 Fed. Reg. at 48,767-78. NuVasive took advantage of those opportunities: it cross-examined Dr. Hynes on his declaration submitted with Medtronic's reply, and it submitted observations on that cross-examination to the Board. But NuVasive never once questioned Dr. Hynes about his testimony that Figure 18 represents a stand-alone embodiment of implant **1000**. Nor did NuVasive press Dr. Hynes about his testimony that implant **1000** as shown in Figure 18 has a width of approximately 12 mm to 16 mm. In fact, NuVasive did not ask Dr. Hynes about Figures 18 and 19 of Michelson at all. *See* A05449-57 & A05483-84 (deposition transcript excerpts showing the discussions of Michelson). NuVasive's motions for observation also said nothing about Figures 18 and 19. *See* A00435-49 (IPR2013-00507, Motion for Observation Regarding Cross-Examination of Richard A. Hynes, M.D.); A06047-60 (IPR2013-00508, Motion for Observation Regarding Cross-Examination of Richard A. Hynes, M.D.). Thus, even when given the opportunity to respond to Medtronic's "new" evidence in the manner suggested by

NuVasive's request for surreplies and motions to strike issued on September 23, 2014. A0368; A05991. NuVasive cross-examined Dr. Hynes on September 30, 2014, A05342, and submitted motions for observation thereafter.

this Court in *Belden*, NuVasive failed to investigate or address the very issue NuVasive now contends warrants reversal. NuVasive's attempts to undo these inter partes reviews should be rejected.

D. The Board Did Not Exceed Its Authority in Confirming the Content of Michelson's Disclosure

Finally, NuVasive argues that the Board created a "new ground" of unpatentability by presenting calculations in the final written decision. Br. at 37-38. NuVasive's arguments lack merit.

NuVasive insinuates that the Board must act as an automaton in conducting a trial proceeding such as inter partes review. But inter partes review is an adjudicatory process, *Abbott Labs.*, 710 F.3d at 1326, and the Board's purpose in the trial is to exercise judgment in determining the ultimate patentability of a claim. Thus, the Board—like any adjudicatory body—may (and should) thoroughly explain its reasoning for concluding that a claim is patentable *vel non*, including its reasons for accepting or rejecting each party's contentions. This exercise does not change or improperly supplement the petitioner's grounds of unpatentability, but merely reflects the Board's expertise "in interpreting record evidence," *Brand v. Miller*, 487 F.3d 862, 869 (Fed. Cir. 2007), and deciding the ultimate question of patentability it is required to make under the law, 35 U.S.C. § 318(a). Indeed, "Board members, because of expertise, may more often find it

easier to understand and soundly explain the teachings and suggestions of prior art without expert assistance.” *Belden*, 805 F.3d at 1079.

And here, the Board used reason and logic to resolve a factual dispute between the parties about the scope and content of the prior art—a task well within its role as a fact-finder. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Board had before it two conflicting interpretations of the dimensions of Michelson’s implant **1000**: NuVasive’s view that Michelson “certainly does not propose any implants with a length to width ratio of 2.5:1,” A00292, and Medtronic’s view that Michelson discloses “long and narrow implants with a length-to-width ratio of 2.5:1 or more,” A00350. The Board did not rely on “speculation” to resolve this conflict, as NuVasive asserts (Br. at 40), but instead drew on “logic, judgment, and common sense”—an approach this Court has endorsed. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1239 (Fed. Cir. 2010).

First, the Board noted that Michelson describes spinal fusion implant **900** as having a preferred width of 26 mm, which “approximates the depth of the vertebrae.” A00009 (quoting A00790, col. 10, ll. 40-41 & 44-47); A00022-23 (same). The Board thusly concluded that the approximate depth of a vertebrae must be 26 mm. A00009; A00023. Next, the Board noted that Michelson describes an alternative implant **1000** that “has a narrower width such that more than one spinal fusion implant . . . may be combined . . . for insertion within the

disc space.” A00009 (quoting A00790, col. 10, ll. 52-54); A00023 (same). The Board thusly concluded that two or more implants **1000** could be used to span the 26 mm vertebral depth. A00009; A00023. The Board then reasoned that if two implants **1000** were used to span that depth, then the width of each implant would be 13 mm (or 26 mm/2 implants). And this number, when multiplied by a factor of 2.5, is less than the length of the implant **1000**. *Id.* The Board therefore found that Michelson’s implant **1000** satisfied the claimed length-to-width ratio of 2.5:1. A00009; A00023 & n.5.

Contrary to NuVasive’s assertion, the Board did not come to this factual finding by way of personal knowledge. Br. at 41 (citing *Brand*, 487 F.3d at 868-69). Nor did the Board attempt to measure Michelson’s figures. Br. at 40. The Board instead used grade-school arithmetic, based on the measurements provided in Michelson’s written description, to make explicit what Michelson already implicitly taught: that the length of implant **1000** is at least 2.5 times its width.

In re Kumar, 418 F.3d 1361 (Fed. Cir. 2005), does not foreclose the Board’s analysis. In *Kumar*, the Board “went off on its own” by disregarding the examiner’s *prima facie* case of obviousness and creating its own, entirely new *prima facie* case based on calculations it performed for the first time on appeal. *Id.* at 1367 (quotation omitted). This Court vacated the Board’s decision, holding that the Board’s “calculations and its decision based thereon” resulted in a new ground

of rejection under the Board's rules and should have been so treated. *Id.* at 1367-68. Thus, by its own terms, *Kumar* involved the Board's authority to enter a new ground of rejection in an *ex parte* examination. And the regulatory scheme governing a new-grounds-of-rejection is clear that those rules apply only to examinations.

Specifically, 37 C.F.R. § 41.50(b) and 37 C.F.R. § 41.77(b) are limited to the USPTO's examination and reexamination regulations, respectively. *See also* 37 C.F.R. §§ 41.30, 41.31(a) (limiting appeals to the Board under subpart B of Part 41 to patent applicants and owners of patents undergoing *ex parte* reexamination); 37 C.F.R. §§ 41.60, 41.61(a)(1) (limiting appeals under Subpart C of Part 41 to patent owners and third-party requesters in *inter partes* reexaminations). In contrast, subparts A and B of Part 42 of the USPTO's regulations—the subparts of title 37 of the Code of Federal Regulations that govern the new AIA proceedings and *inter partes* review—do not include a new-grounds-of-rejection rule. Because *Kumar* speaks to the Board's use of a new ground of rejection, its holding does not assist NuVasive.

V. CONCLUSION

NuVasive received notice of the proposed grounds of unpatentability and had more than one opportunity to respond to them before the Board issued its final written decisions. In fact, NuVasive disputed the factual issue that is now the

centerpiece of its due-process challenge. The Board, far from abusing its discretion, provided NuVasive a full and fair opportunity to present its case. The Board's decisions should therefore be affirmed.

Respectfully submitted,

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/s/ Kristi L. R. Sawert

THOMAS W. KRAUSE
Acting Solicitor

SCOTT C. WEIDENFELLER
Acting Deputy Solicitor

KRISTI L. R. SAWERT
JOSEPH MATAL
Associate Solicitors

Office of the Solicitor
U.S. Patent and Trademark Office
Mail Stop 8, P.O. Box 1450
Alexandria, Virginia 22313-1450

*Attorneys for the Director of the
United States Patent and
Trademark Office*

CERTIFICATE OF COMPLIANCE

I certify pursuant to Fed. R. App. Proc. 32(a)(7) that the foregoing BRIEF FOR INTERVENOR—DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE complies with the type-volume limitation required by the Court's rule. The total number of words in the foregoing brief, excluding the table of contents and the table of authorities, is 8,785 words as calculated using the Word® software program.

/s/ Kristi L. R. Sawert

Kristi L. R. Sawert
Associate Solicitor

CERTIFICATE OF SERVICE

I hereby certify that on March 21, 2016, I electronically filed the foregoing
BRIEF FOR INTERVENOR – DIRECTOR OF THE UNITED STATES
PATENT AND TRADEMARK OFFICE using the Court’s CM/ECF filing
system. Counsel for the parties was electronically served by and through the
Court’s CM/ECF filing system per Fed. R. App. P. 25 and Fed. Cir. R. 25(a) and
25(b).

/s/ Kristi L. R. Sawert

Kristi L. R. Sawert

Associate Solicitor

U.S. Patent and Trademark Office

Mail Stop 8, P.O. Box 1450

Alexandria, VA 22313-1450